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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,453	07/29/2003	Rossella Musa	241019US0DIV	4847

22850 7590 04/22/2005

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EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,453	MUSA ET AL:	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14,15,18-33 and 35-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14,15,18-33 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/926,105.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, both received on 21 January 2005.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 17 and 34 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Staniforth and Sarlikiotis *et al.* is rendered moot with the cancellation of those claims.

The rejection of Claims 11, 14, 15, 18-33, 35, and 36 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Staniforth and Sarlikiotis *et al.* is maintained.

Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Staniforth (U.S. Patent No. 6,153,224) and Sarlikiotis *et al.* (U.S. Patent No. 6,284,287)

The Staniforth patent teaches a process for treating inhaler carrier particles in order to allow a higher respirable fraction of the active substance (See Abstract). The carrier particles are preferably lactose particles, such as alpha lactose monohydrate (See Column 4, Lines 35-41; and Example 1, Column 10, Line 67). The preferred range of particle sizes lie in the range of 60 microns to 180 microns; Example 1 uses particles in the range of 90 microns to 125 microns (See

Column 4, Lines 42-57; and Column 11, Lines 3-22). The carrier particles include additives, which promote the release of the active substance particles from the carrier particles upon actuation of the inhaler (See Column 3, Lines 3-6). Suitable additive materials include stearic acid, magnesium stearate, and sodium stearyl fumarate (See Column 5, Lines 36-55). In most cases, the amount of additives does not exceed more than 2% by weight (See Column 4, Lines 6-14). The mass median diameter of the active substance particles is preferably less than 5 microns (See Column 7, Lines 36-43). Suitable active substances disclosed by the patent include salmeterol, salbutamol, ipratropium bromide (See Column 7, Lines 44-64), and beclomethasone dipropionate (See Example 1, Column 11, Line 43). The patent also discusses the treatment of the carrier particles in order to alleviate surface irregularities. In the course of the treatment, asperities of the carrier particles are removed as smaller grains and attach themselves to high surface energy sites, without significantly changing the particle size of the carrier particles themselves (See Column 8, Lines 51-65; Column 9, Lines 6-37; and Column 10, Lines 1-27). The patent states that the carrier particles are treated with the addition of the additives, and may be mixed for 0.1 hours to 0.5 hours (6 to 36 minutes), using a tumbling blender, such as a Turbula Mixer (See Column 8, Lines 47-50; and Example 1, Column 11, Lines 23-28). Alternatively, the carrier may be treated alone, before the addition of any additive; or with the addition of both the additive and the active substance (See Column 8, Line 66 to Column 9, Line 5). The treatment may also be carried out in a mill, such as a ball mill, for a period of time ranging from 0.25 hours (15 minutes) to 6 hours (360 minutes) (See Column 9, Lines 38-67).

Staniforth does not give a specific example where the treatment of the carrier particles is carried out for 30 minutes, nor does it teach the use of a sigma blade mixer, running as a speed between 100 to 300 rpm.

The Sarlikiotis *et al.* patent teaches a formulation for use in an inhaler, which comprises active substance particles coating carrier particles. Substances suitable as carrier particles include lactose, as well as its derivatives (See Column 4, Lines 14-16). The active substance used should have a particle size of 0.01 microns to 10 microns in order to ensure sufficient attraction to the carrier particles (See Column 2, Lines 61-64). The list of suitable active substances include ipratrpium bromide, oxytropium bromide, beclomethasone, budesonide, flunisolide, formoterol, salbutamol, salmeterol, and terbutalin; esters of the drugs may be used as well, including dipropionate (See Column 3, Lines 24-65). Preparation of the formulation is carried out in a mixer, such as a tumble mixer, a rotary mixer, or a high-speed mixer; the Turbula Mixer is given as an example of a tumble mixer (See Column 4, Lines 32-37). Both the active substance and the carrier particles are mixed in the mixer until the carrier particles are coated with the active substance, with "the fine fraction gradually disappearing and round, coated particles resulting" (See Column 4, Lines 38-41). Examples are given where the preparation is carried out in a mixer, for 30 minutes (See Examples 1 and 2).

It would be obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Staniforth in view of Sarlikiotis *et al.* Sarlikiotis *et al.* teach a mixing time of 30 minutes, as well as an expanded list of suitable active substances. Furthermore, it would be obvious that the mixing process described in Sarlikiotis *et al.* would modify the surface properties of the carrier particles, as described in Staniforth. It is the opinion of the examiner

that there is no criticality to the limitations of Claim 20, as the formulation of inhaler particles with improved surface properties is successfully carried out, as shown in Staniforth and Sarlikiotis *et al.*, without the specific use of a sigma blade mixer running at 100 to 300 rpm. Thus, the invention, as a whole, is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The previous rejection of Claims 11, 14, 15, and 17-36 under the judicially created doctrine of obviousness-type double patenting over Claims 1-21 of U.S. Patent No. 6,641,844 is hereby withdrawn.

Claims 11, 14, 15, 18-33 and 35-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 of U.S. Patent No. 6,641,844. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to processes for the modification of surface properties of particles for use as carrier particles for the pulmonary administration of micronized drugs by means of dry powder inhalers. In certain embodiments of both processes, the carrier

particles consist of α-lactose monohydrate. In other embodiments of both processes, the starting diameter of the carrier particles lies between 90 and 150 μm. Both processes also use the same broad group of active ingredients and the same broad group of lubricants.

More specifically, newly drafted independent Claim 37 is drawn to a process comprising the steps of mixing carrier particles having a starting diameter that lies between 20 and 1,000 microns with fine carrier particles having a diameter of less than 10 microns, with this step being carried out in a mixer with a stationary or rotating body equipped with a rotating element or in a high-energy mixer. Newly drafted Claim 38 further adds the limitation where the fine carrier particles are produced *in situ*. These claims are considered to be obvious in view of Claim 20 of U.S. Patent No. 6,641,844, which broadly contains limitations very similar to those listed above.

Response to Arguments

Applicant's arguments filed 21 January 2005 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., powder flow properties as measured by the Carr's index, and the respirable fraction of the drug) are not recited in the rejected claims. Although the claims are interpreted in light of the specification,

limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Concerning the applicant's arguments against the disclosure of the prior art, it is the position of the examiner that as the particular apparatus used in the prior art broadly accomplishes the same goal, namely the detachment of small grains from carrier particles in order to improve their properties as inhalant carriers, the particular selection of the apparatus does not impart patentability to the instant claims.

Regarding the double patenting rejection of record, a new rejection is made for the reasons detailed above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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